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10/563,551

08/17/2006

Jeak Ling Ding

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,551	<b>Applicant(s)</b> DING ET AL.	
	<b>Examiner</b> Patricia A. Duffy	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16,32-34 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16,32-34 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1-4-06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-4-06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The response and amendment filed 12-30-08 has been entered into the record. Claims 1-16, 32-34 and 36-38 are pending. Claims 17-31 and 35 have been cancelled.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Drawings***

The drawings in this application have been accepted. No further action by Applicant is required.

#### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Information Disclosure Statement***

The information disclosure statement filed 1-4-06 has been considered. An initialed copy is enclosed.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Election/Restrictions***

Applicant's election of Group I in the reply filed on 12-30-08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Double Patenting***

Applicant is advised that should claim 36 be found allowable, claim 37 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. Therefore, the text of the instruction per se does not distinguish the kit of claims 36 and 37 as it does not lend patentable weight. The proteins of the claimed articles remain fully functional absent the printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15, 16 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29 and 30 of U.S. Patent No. 6,719,973 issued April 13, 2004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species of sushi S3 peptide linked to green fluorescent protein of the claims anticipates the broadly claimed labeled peptides.

Claims 1-8, 12, 14 and 36-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12, 20 and 27-36 of U.S. Patent No. 6,719,973 in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002)..

Ding et al teach recombinant production of S3 peptides by fusion to a green fluorescent protein. Ding et al teach synthetic production of and immobilization on an Agarose solid surface/medium/resin for the removal of endotoxin (see Example 11; column 22). Ding et al differ by not producing the S3 peptide as a multimer either by recombinant or chemical means.

Tam et al teach an approach for designing antimicrobial peptides is to exploit mechanisms of their action and recognizing conserved motifs. Some well studied motif recognizing proteins for LPS include LPS binding protein (LBP), CD14 and toll like LPS receptors. Tam et al teach design of novel antimicrobial peptides and their assembly into dendrimeric peptides or repeating linear peptides. Tam et al teach repeating R4 peptides containing two, four or eight copies of the R4 peptides (see page 927, column 2, to page 928 column 1. Tam et al teach that linearly repeating antimicrobial peptides improved as the molecular size increased (see page 927, column 2, last paragraph). Tam et al teach that dendrimeric peptides can have antimicrobial activity as compared to the monomer (see abstract). Tam et al teach that dendrimeric peptides and linear peptides retain antimicrobial activity.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to chemically synthesize or recombinantly produce repeating linear peptides of two, four or eight copies of the S3 peptide of Ding et al and optionally immobilize the repeating S3 peptide on a solid medium because Tam et al teach that dendrimeric or repeating linear peptides of antimicrobial peptides have use as antimicrobial agents and can have increased antimicrobial activity compared to the monomer one would have been motivated to produce the repeating linear peptide in order to optimize endotoxin neutralization. It also would have been *prima facie* obvious to assemble the final repeating linear peptide into a kit format with a piece of paper identifying the contents of the kit for neutralization of endotoxin and assembly into a kit

Art Unit: 1645

format of reagents is routine in the art and provides for convenience and economy to the consumer.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14-16, 32-34 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polypeptide comprising more than one "S3 peptide". The description of the specification indicates that the peptide known as SEQ ID NO:1 an S3 peptide binds to lipopolysaccharide and have activity in detecting and removing LPS from solutions. However, the art teaches that S3 can represents multiple different entities in the art, including ribosomal protein S3, pertussis toxin S3 subunit, peptidase S3 domains

and S3 domain protein motifs all which have different primary amino acid structures. The specification does not define S3 as SEQ ID NO:1.

The claims are drawn to any S3 peptide repeat structure in the same polypeptide. The specification teaches that the S3 peptide monomer of SEQ ID NO:1 binds lipopolysaccharide. The specification teaches that S3 multimers have lipopolysaccharide (LPS) binding activity. The specification does not place any structure, chemical or functional limitations on the variants of S3. The recitation of "S3" does not convey a common structure or function because the term "S3" represents multiple different entities in the art, including ribosomal protein S3, pertussis toxin S3 subunit, peptidase S3 domains and S3 domain protein motifs. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. Since the disclosure fails to describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant and is insufficient to describe the genus of polypeptides that comprise more than one S3 peptide that function equivalently. One of skill in the art would reasonably conclude that the disclosure of a single S3 peptide set forth in SEQ ID NO:1, fails to provide a representative number of species of S3 peptides to describe the claimed genus. Applicants were not in possession of the claimed genus because the specification does not convey to one of skill in the art a representative number of variants in structure and function of any such polypeptide that has the claimed structure and function. The genus of polypeptides with the claimed S3 structure is substantial and highly variant because the polypeptides do not have a common structure and function. The recitation of "S3" does not convey a common



structure nor a common function. As such, generic polypeptide sequences that are unrelated via structure and function are highly variant and not conveyed by way of written description by the specification at the time of filing. As such the specification lacks written description for the highly variant genus and one skilled in the art would not recognize that applicants had possession of the genus of claimed polypeptides for use in an LPS binding assay, therapy or removal as contemplated by the specification. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

Claims 1-16, 32-34 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "S3" is prima facie indefinite because S3 can represents multiple different entities in the art, including ribosomal protein S3, pertusis toxin S3 subunit, peptidase S3 domains and S3 domain protein motifs. As such, the skilled artisan would not be readily apprised of the metes and bounds of the structure of the "S3" peptide. Limitations from the specification are not read into the claims. As to claim 13, it is unclear if the sequence is parenthesis is limiting. If applicants intend to be limiting, amending the claim to recite " the polypeptide of claim 6 comprising the amino acid sequence that is set forth in SEQ ID NO:9" would obviate the confusion.

***Claim Rejections - 35 USC § 102 or 103***

*It is noted that the Canadian provisional document provides conception by way of written description for a tetrameric or octameric repeat of S3 at page 8, lines 21-32. Therefore claims 1-5, 8-16, 32-34 and 38-38 claims do not enjoy priority to the foreign priority document filed 7-4-03. Consequently, these claims are given the priority of the international document which is 7-2-04. Should Applicants believe that the indicated claims have support in the priority document, they should point to the page and line number where conception by way of written description can be found. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a)

shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tan et al (The FASEB Journal, 14:1801-1813, September 2000).

Tan et al teach sushi S3 peptide linked to green fluorescent protein see paragraph bridging pages 1804-1005. Green fluorescent protein fluoresces when subjected to the correct wavelength of blue light. As such, the recombinant protein of the art anticipates the claims.

Claims 1-5, 8, 10 and 11 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Li et al (Protein Engineering, 16(8):629-635, August 2003).

Li et al teach recombinant rS3-4mer linked by acid labile Asp-Pro bonds (see page 630-631 (material and methods section). Li et al teach digestion of the 4-mer to 3-mers, 2-mers and monomers (see page 633, column 1 Figure 3). Li et al teach that the peptides bind to LPS and inhibit endotoxin induced LAL reaction and hTNF-alpha release from THp-1 cells.

Claims 15, 16 and 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Ding et al (US Patent No. 6,719,973 issued April 13, 2004 with priority to July 26, 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference

was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ding et al teach the sushi peptide S3 labeled with a recombinant binding peptide such as green fluorescent protein, alkaline phosphatase, peroxidase or luciferase (see claims 29 and 30. Green fluorescent protein fluoresces when exposed to blue light. Ding et al teach the labled S3 peptide linked to DADPA-Agarose CL-6B activated resins for removal of endotoxin from samples (see column 22, Example 11).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 12, 14 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al (US Patent No. 6,719,973 issued April 13, 2004 with priority to July 26, 2000) in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002).

Ding et al teach recombinant production of S3 peptides by fusion to a green fluorescent protein. Ding et al teach synthetic production of and immobilization on a solid surface/medium/resin for the removal of endotoxin (see Example 11; column 22). Ding et al do not teach the resin agarose. Ding et al differ by not producing the S3 peptide as a multimer either by recombinant or chemical means.

Tam et al teach an approach for designing antimicrobial peptides is to exploit mechanisms of their action and recognizing conserved motifs. Some well studied motif recognizing proteins for LPS include LPS binding protein (LBP), CD14 and toll like LPS receptors. Tam et al teach design of novel antimicrobial peptides and their assembly into dendrimeric peptides or repeating linear peptides. Tam et al teach repeating R4 peptides containing two, four or eight copies of the R4 peptides (see page 927, column 2, to page 928 column 1. Tam et al teach that linearly repeating antimicrobial peptides improved as the molecular size increased (see page 927, column 2, last paragraph). Tam et al teach that dendrimeric peptides can have antimicrobial activity as compared to the monomer (see abstract). Tam et al teach that dendrimeric peptides and linear peptides retain antimicrobial activity.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to chemically synthesize or recombinantly produce repeating linear peptides of two, four or eight copies of the S3 peptide of Ding et al and optionally immobilize the repeating S3 peptide on a solid medium because Tam et al teach that dendrimeric or repeating linear peptides of antimicrobial peptides have use as antimicrobial agents and can have increased antimicrobial activity compared to the monomer one would have been motivated to produce the repeating linear peptide in order to optimize endotoxin neutralization. It also would have been *prima facie* obvious to

assemble the final repeating linear peptide into a kit format with a piece of paper identifying the contents of the kit for neutralization of endotoxin and assembly into a kit format of reagents is routine in the art and provides for convenience and economy to the consumer.

Claims 1-8, 12, 14 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan et al (The FASEB Journal, 14:1801-1813, September 2000) in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002).

Tan teach that the S3 peptide can bind and neutralize LPS. Tan et al also teach the sushi S3 peptide corresponding to residues 268-301 of CrFC was synthesized and purified by Genemed Synthesis Inc. (see page 1803, column 1, see "Peptides"). Tan et al teach recombinant production of the sushi S3 peptide linked to green fluorescent protein see paragraph bridging pages 1804-1005. Green fluorescent protein fluoresces when subjected to the correct wavelength of blue light. Green fluorescent protein fluoresces when subjected to the correct wavelength of blue light. Tan et al teach that S3 peptide provides for neutralization of endotoxin. Tan et al differ by not producing the S3 peptide as a multimer either by recombinant or chemical means.

Tam et al teach an approach for designing antimicrobial peptides is to exploit mechanisms of their action and recognizing conserved motifs. Some well studied motif recognizing proteins for LPS include LPS binding protein (LBP), CD14 and toll like LPS receptors. Tam et al teach design of novel antimicrobial peptides and their assembly into dendrimeric peptides or repeating linear peptides. Tam et al teach repeating R4 peptides containing two, four or eight copies of the R4 peptides (see page 927, column 2, to page 928 column 1. Tam et al teach that linearly repeating antimicrobial peptides improved as the molecular size increased (see page 927, column 2, last paragraph). Tam et al teach that dendrimeric peptides can have antimicrobial activity as compared to the monomer

Art Unit: 1645

(see abstract). Tam et al teach that dendrimeric peptides and linear peptides retain antimicrobial activity.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to chemically synthesize or recombinantly produce repeating linear peptides of two, four or eight copies of the S3 peptide of Tan et al because Tam et al teach that dendrimeric or repeating linear peptides of antimicrobial peptides have use as antimicrobial agents and can have increased antimicrobial activity compared to the monomer one would have been motivated to product the repeating linear peptide in order to optimize endotoxin neutralization. It also would have been *prima facie* obvious to assemble the final repeating linear peptide into a kit format with a piece of paper identifying the contents of the kit for neutralization of endotoxin and assembly into a kit format of reagents is routine in the art and provides for convenience and economy to the consumer.

#### ***Status of the Claims***

All claims stand rejected. Claims 9 and 13 are free of the art.

#### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-

Art Unit: 1645

0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner